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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,692	01/22/2004	Giulia C. Kennedy	PP01575.005	8429

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EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/763,692	KENNEDY, GIULIA C.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-3, drawn to a human HX2004-6 polypeptide, classified in class 530, subclass 350.

Group II. Claims 4-12, drawn to a human HX2004-6 polynucleotide, a vector, a host cell, and a method for producing a human HX2004-6 polypeptide, classified in class 536, subclass 23.1

Group III. Claim 13, drawn to an antibody that binds specifically to the human HX2004-6 polypeptide, classified in class 530, subclass 387.1.

Group IV. Claims 14-17, drawn to a method for detecting the HX2004-6 polynucleotide in pancreas tissue, classified in class 435, subclass 6.

Group V. Claims 14-17, drawn to a method for detecting the HX2004-6 polynucleotide in colon tissue, classified in class 435, subclass 6.

Group VI. Claims 14-17, drawn to a method for detecting the HX2004-6 polynucleotide in breast tissue, classified in class 435, subclass 6.

Group VII. Claim 18, drawn to a method for detecting the HX2004-6 polypeptide in pancreas tissue, classified in class 435, subclass 7.1.

Group VIII. Claim 18, drawn to a method for detecting the HX2004-6 polypeptide in colon tissue, classified in class 435, subclass 7.1.

Group IX. Claim 18, drawn to a method for detecting the HX2004-6 polypeptide in breast tissue, classified in class 435, subclass 7.1.

Group X. Claims 19-20, drawn to a method for identifying an agent that modulates HX2004-6 mRNA, classified in class 435, subclass 6.

Group XI. Claims 19, 21, drawn to a method for identifying an agent that modulates HX2004-6 polypeptide, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons.

Inventions I-III are patentably distinct products.

A. The polypeptide of group I and polynucleotide of group II are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules. Furthermore, the information provided by the polynucleotide of group II can be used to make a materially different polypeptide than that of group I. For example, a nucleic acid which hybridizes to SEQ ID NO: 1, even under stringent conditions, encompasses molecules which contain point mutations, splice sites, frameshift mutations or stop codons which would result in use of a different open reading frame, and thus encode a protein that lacks any significant structure in common with SEQ ID NO. 2. In addition, while a polypeptide of group I can be made by methods using some, but not all, of the polynucleotides that fall within the scope of group I, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of groups I and II are patentably distinct.

Furthermore, searching the inventions of groups I and II together would impose a serious

search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of groups I and II together.

B. The polypeptide of group I and the antibody of group III are patentably distinct for the following reasons:

While the inventions of both group I and group III are polypeptides, in this instance the polypeptide of group I is a single chain molecule, whereas the polypeptide of group III encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of group I and the antibody of group III are structurally distinct molecules. Therefore the polypeptide and antibody are patentably distinct.

Furthermore, searching the inventions of group I and group III would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different

searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of group III. Furthermore, antibodies which bind to an epitope of a polypeptide of group II may be known even if a polypeptide of group I is novel. In addition, the technical literature search for the polypeptide of group I and the antibody of group III are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of the sequence of their binding target.

C. The polynucleotide of group II and the antibody of group III are patentably distinct for the following reasons. The antibody of group III includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides, such as the antibody of group III which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group II will not encode an antibody of group III, and the antibody of group III cannot be encoded by a polynucleotide of group II. Therefore the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group II and group III would impose a serious search burden since a search of the polynucleotide of group II is would not be used to determine the patentability of an antibody of group III, and vice-versa.

D. Inventions IV-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of detecting a polypeptide in pancreas, colon or breast cancer, using an antibody, the method of detecting a polynucleotide in pancreas, colon or breast cancer, using a polynucleotide, and the method of screening an agent that modulates a polypeptide or a polynucleotide are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs its function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for detecting a polypeptide or a polynucleotide differ significantly for each of the materials. For diagnosis using the polynucleotide, hybridization may be used. For diagnosis using the antibody, quantitation of labeled antibody may be used. Therefore, each method is divergent in materials and steps. For these reasons the Inventions IV-XI are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups IV-XI have a separate status in the art as shown by their different classifications. There may be journal articles devoted solely to detecting the presence of a polypeptide, or a polynucleotide, which would not have described methods of identifying agents that modulate the polypeptide or polynucleotide, or vice versa. Similarly, there may be journal articles devoted solely to detecting the presence of a polypeptide in a cancer, which would not have described methods of detecting the presence of said polypeptide in another cancer, or

methods of detecting the presence of a polynucleotide in said cancer or in another cancer. As such, it would be burdensome to search the inventions of Groups IV-XI together.

E. Inventions I and VII-IX, XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used to make an antibody as opposed to its use in a method of detecting disease.

Searching the inventions of Groups I and VII-IX, XI together would impose serious search burden. The inventions of Groups I and VII-IX, XI have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polypeptides and the method of detecting a cancer, or screening a modulator of the polypeptide, using a polypeptide are not coextensive. The search for groups VII-IX, XI would require a text search for the method of detecting a cancer or screening a modulator of the polypeptide, in addition to a search for SEQ ID No 2. Moreover, even if the polypeptide product were known, the method of detecting a cancer, or screening a modulator of the polypeptide, which uses the product may be novel and unobvious in view of the preamble or active steps.

F. Inventions II and IV-VI, X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the polynucleotides of group II can be used to make recombinant proteins as opposed to its use in diagnosing a cancer.

Searching the inventions of Groups II and IV-VI, X together would impose serious search burden. The inventions of Groups II and IV-VI, X have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polynucleotides and the method of diagnosing a cancer, or screening a modulator of the polynucleotide, using a polynucleotide are not coextensive. Group II encompasses molecules which are claimed in terms of hybridization in regard to reference sequence SEQ ID NO 1, which are not required for the search of Groups IV-VI, X. In contrast, the search for groups IV-VI, X would require a text search for the method of diagnosing a cancer, or screening a modulator of the polynucleotide, in addition to the search of SEQ ID No 1 or complements thereof. Prior art which teaches a polynucleotide would not necessarily be applicable to the method of using the polynucleotide. Moreover, even if the polynucleotide product were known, the method of diagnosis a cancer or screening a modulator, using the product may be novel and unobvious in view of the preamble or active steps.

G. Inventions III and VII-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used to make an affinity column, as opposed to being used to diagnose a cancer.

Searching the inventions of Groups III and VII-IX together would impose serious search burden. The inventions of Groups III and VII-IX have a separate status in the art as shown by their different classifications. Moreover, the search for groups VII-XI would require a text search for the method of diagnosing a cancer, in addition to the search of the antibody. Moreover, even if the antibody product were known, the method of diagnosis which uses the product may be novel and unobvious in view of the preamble or active steps.

H. Inventions I, III and (IV-VI, X) are unrelated because the product of groups I, III is not used or otherwise involved in the processes of groups IV-VI, X.

Inventions II and (VII-IX, XI) are unrelated because the product of group II is not used or otherwise involved in the processes of groups VII-IX, XI.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER

MINH TAM DAVIS

September 14, 2006